



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/089,501

04/22/2002

Hiroyuki Saito

053-466-0325

9449

22428

7590

06/04/2009

FOLEY AND LARDNER LLP

SUITE 500

3000 K STREET NW

WASHINGTON, DC 20007

EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

06/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/089,501

Applicant(s)

SAITO ET AL.

Examiner

Michael Burkhardt

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49, 52, 53 and 55 is/are rejected.
- 7) ☒ Claim(s) 51, 54 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt and entry of the amendment dated 3/23/2009 is acknowledged. After entry of the amendment, claims 45-49 and 51-56 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

Claims 45-49, 52, 53 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al (U.S. Patent 5,986,065, EFD 3/10/1997). **This rejection is maintained for reasons made of record in the Office Action dated 4/4/2008, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 3/23/2009 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Wong fails to teach suppressing hypertrophy of the vascular intima (e.g. restenosis), rather, Wong is directed to treating short term active thrombosis; 2) the skilled artisan would recognize that restenosis can occur early or late, and that Wong et al only teach treating early restenosis; 3) the claimed methods are clearly directed to late stage restenosis; 4) the claim preamble recites "a patient in need thereof" and thus must be given patentable weight; 5) the influence of anti-TF antibodies on the proliferation of intima tissue was not known prior to the instant invention, and the use of US 6,287,794 by the Examiner to provide evidence of such is incorrect.

Regarding 1) - 4), again, applicants confusingly equate "hypertrophy of the vascular intima" with restenosis, then appear to argue that restenosis is thrombosis, or undesirable blood

clotting. The two are quite different as applicants point out. Restenosis, absent a definition in the specification, is loosely defined as reoccurrence of stenosis (a narrowing of a vessel) after corrective surgery or treatment. Wong et al clearly teach treating restenosis with anti-TF antibodies for reasons made of record, thus, the assertion that Wong only teaches treating thrombosis or blood clotting is incorrect. Furthermore, this is all that is required to anticipate the instant claims, as restenosis is a prime example of "hypertrophy of the vascular intima", a term also not defined in the specification. "Hypertrophy" is, loosely, a growth of non-tumorous nature and "intima" is considered to be the innermost membrane of a vein, vessel, etc. This is considered to encompass both early and late stage restenosis, absent a more precise definition of the claimed term "hypertrophy of the vascular intima" either in the specification or prior art. It thus encompasses patients in need of treatment in both early and late stage restenosis.

Since the antibodies of Wong et al have the same activity as those instantly claimed, they inherently have the same effect upon restenosis as the claimed antibodies. Applicants present no rebuttal to this fact.

Further regarding 2) and 3), in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treating late stage restenosis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding 5), as previously stated, this recognition is not required to anticipate the instant claims. The teachings of the '794 patent relate directly to the broad term "hypertrophy of the

vascular intima" for reasons set forth above (i.e. the term encompasses restenosis in all its forms), and teach using antibodies directed to the very same TF/Factor VIIa complex as recited in the claims and those taught by Wong et al.

Allowable Subject Matter

Claims 51, 54 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Burkhart whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhart/
Primary Examiner, Art Unit 1633